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Attorney Docket No. 54275.8021.US01

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: JAMES M. LIPTON

APPLICATION No.: 10/774,271

FILED: FEBRUARY 6, 2004

FOR: **METHODS AND COMPOUNDS FOR TREATING  
MALABSORPTION DISEASES AND  
INFLAMMATORY CONDITIONS OF THE  
GASTROINTESTINAL TRACT**

EXAMINER:

ART UNIT: 1651

CONF. NO: 8459

**Information Disclosure Statement Within Three Months of  
Application Filing or Before First Action – 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. Timing of Submission

This information disclosure is being filed within three months of the filing date of this application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever occurs last [37 C.F.R. § 1.97(b)]. The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

2. Cited Information

Copies of all cited references are enclosed, except for reference "AE" which refers to a large core text which is basic information only.

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Certificate of Mailing

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

June 29, 2004  
Date of Deposit

Debbie Gilbert  
Debbie Gilbert

3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment

No fees are believed due because this Information Disclosure Statement is being filed before the mailing date of the first Office Action.

Dated: 6-29, 2004

Respectfully submitted,

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				Application Number	10/774,271
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				Examiner Name	
Sheet	1	of	4	Attorney Docket No.	54275.8021.US01

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	U.S. Patent or Application		Name of Patentee or Inventor of Cited Document	Date of Publication or Filing Date of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		NUMBER	Kind Code (if known)				
	AA	5,157,023		Lipton	03/21/91		

  

FOREIGN PATENT DOCUMENTS							
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OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.					
	AB	Abdel-Malek, "Melanocortin receptors: their functions and regulation by physiological agonists and antagonists." <i>Cell. Mol. Life Sci.</i> 58:434-441 (2001).					
	AC	Andreoli et al., "Cecil Essentials of Medicine." pp.267-270, (W.B. Saunders Co. 1986).					
	AD	Beckett CG et al., "Gluten-induced nitric oxide and pro-inflammatory cytokine release by cultured celiac small intestinal biopsies." <i>Eur J Gastroenterol Hepatol</i> 1999; 11:529-535.					
	AE	Braunwald et al., "Harrison's Principles of Internal Medicine." pp. 1165-1674, (15 <sup>th</sup> Ed. McGraw Hill, 2001). <u>[Book – not included.]</u>					
	AF	Catania et al., " $\alpha$ -MSH in Normal Human Physiology and Disease States." <i>Trends Endocrinol Metab</i> , 11:304-308 (2000).					
	AG	Catania et al., " $\alpha$ -Melanocyte Stimulating Hormone in the Modulation of Host Reactions." <i>Endocr Rev</i> 4:564-576 (1993).					

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<p>*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to application(s).</p>	

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Form PTO-1449 (Modified) (Use several sheets if necessary)				<b>COMPLETE IF KNOWN</b>	
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	AH	Catania et al., "The Anticytokine Neuropeptide $\alpha$ -MSH in Synovial Fluid of Patients with Rheumatic Diseases: Comparisons with Other Anticytokine Molecules." <i>Neuroimmunomodulation</i> 1:321-328 (1994).			
	AI	Catania et al., "The Neuropeptide $\alpha$ -MSH has Specific Receptors on Neutrophils and Reduces Chemotaxis In Vitro." <i>Peptides</i> 17:675-679 (1996).			
	AJ	Chomczynski et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol -Chloroform Extraction." <i>Analytical Biochemistry</i> , 162:156-159 (1987).			
	AK	Deeter et. al., "Antipyretic Properties of Centrally Administered $\alpha$ -MSH Fragments in the Rabbit." <i>Peptides</i> 9, 1285-1288 (1989).			
	AL	Eberle, "The Melanotropins", Basel (ed. S. Karger) 1988.			
	AM	Ferguson et al., "Quantitation of Intraepithelial Lymphocytes in Human Jejunum." <i>Gut</i> ; 12:988-994 (1971).			
	AN	Ferguson et al., "Cell-mediated Immunity to Gliadin Within the Small-intestinal Mucosa in Coeliac Disease." <i>Lancet</i> , 1:895-897 (1975).			
	AO	Hiltz, M.E., "Anti-inflammatory Activity of $\alpha$ -MSH (11-13) Analogs: Influences of Alterations in Stereochemistry." <i>Peptides</i> 12:767-771 (1991).			
	AP	Holdeman et al., "Antipyretic Activity of a Potent $\alpha$ -MSH Analog." <i>Peptides</i> 6:273-275 (1985).			
	AQ	Ichiyama et al., " $\alpha$ -Melanocyte-stimulating hormone Inhibits NF- $\kappa$ B Activation and I $\kappa$ B <sub>a</sub> Degradation in Human Glioma Cells and in Experimental Brain Inflammation." <i>Exp. Neurol.</i> 157:359-365 (1999).			
	AR	Kennedy, J., Natural Health, 2002. < <a href="http://www.atlantisherbs.com/Articles/artichokeIBS.htm">http://www.atlantisherbs.com/Articles/artichokeIBS.htm</a> >.			

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	AS	Lipton et al., "Anti-inflammatory actions of the neuroimmunomodulator $\alpha$ -MSH." <i>Immunol Today</i> , 18:140-145 (1997).			
	AT	Lipton et al., "Anti-inflammatory Effects of the Neuropeptide $\alpha$ -MSH in Acute, Chronic, and Systemic Inflammation." <i>Ann N Y Acad Sci.</i> , 741:137-148 (1994).			
	AU	Macaluso et al., "Anti- inflammatory Influences of $\alpha$ -MSH Molecules: Central Neurogenic and Peripheral Actions." <i>J Neurosci</i> . 14:2377-2382 (1994).			
	AV	Manna et al., " $\alpha$ -Melanocyte-stimulating hormone Inhibits the Nuclear Transcription Factor NF- $\kappa$ B Activation Induced by Various Inflammatory Agents." <i>J Immunol.</i> , 161:2873-2880 (1998).			
	AW	Mason et al., "Modulation of IL-1, Tumor Necrosis Factor, and C5A-Mediated Murine Neutrophil Migration by $\alpha$ -MSH." <i>J Immunol.</i> ; 142:1646-1651 (1989).			
	AX	Nilsen et al., "Gluten Induces An Intestinal Cytokine Response Strongly Dominated by Interferon Gamma in Patients with Celiac Disease." <i>Gastroenterology</i> ; 115:551-563 (1998).			
	AY	Oktar et al., "The Effect Of $\alpha$ -Melanocyte Stimulating Hormone on Colonic Inflammation in The Rat." <i>Peptides</i> , 21:1271-1277 (2000).			
	AZ	Paulley et al., "Observations on the Aetiology of Idiopathic Steatorrhoea." <i>Br. Med. J.</i> ; 2:1318-1321 (1954).			
	BA	Przemioslo et al., "Raised Pro-Inflammatory Cytokines Interleukin 6 and Tumour Necrosis Factor $\alpha$ In Coeliac Disease Mucosa Detected by Immunohistochemistry." <i>Gut</i> , 35:1398-1403 (1994).			
	BB	Rajora et al., " $\alpha$ -MSH Modulates Experimental Inflammatory Bowel Disease." <i>Peptides</i> , 18:381-385 (1997)			
	BC	<i>Remington's Pharmaceutical Sciences</i> (Mack Publishing Co., 18 <sup>th</sup> ed. 1990).			

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	BD	Schuppan, "Current Concepts of Celiac Disease Pathogenesis." <i>Gastroenterology</i> , 119:234-242 (2000). <span style="float: right;">T</span>		
	BE	Star et al., "Evidence of Autocrine Modulation of Macrophage Nitric Oxide Synthase by $\alpha$ -Melanocyte-Stimulating Hormone." <i>Proc Natl Acad Sci USA</i> , 92:8016-8020 (1995). <span style="float: right;">T</span>		
	BF	Taherzadeh et al., " $\alpha$ -MSH and its Receptors in Regulation of Tumor Necrosis Factor- $\alpha$ By Human Monocyte/Macrophages." <i>Am J Physiol</i> ; 276:R1289-R1294 (1999). <span style="float: right;">T</span>		
	BG	Yardley et al., "Celiac Disease: A Study of the Jejunal Epithelium Before and After a Gluten Free Diet." <i>New Engl. J. Med.</i> ; 267:1173-1179 (1962). <span style="float: right;">T</span>		

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